Current Thinking on the use of Chorhexidine as an arm preparation for Donor Phlebotomy. Leslie Holness, MD, Medical Officer, CBER /FDA

Background:

For the past 50 years the preferred skin preparation for phlebotomy for blood donation has been PVP-iodine or Povidone Iodine. More recently 2% tincture of iodine in 70 % alcohol has also been recommended. Most are available in prepackaged single use kits labeled for blood donor collection. Green soap followed by acetone alcohol was routinely used as an arm scrub for donors allergic to iodine.

In July of 2000, The Center for Drugs (CDER) approved a 2% Chlorhexidine Gluconate in 70% alcohol preparation as an over the counter drug (OTC) for skin preparation prior to surgery.

FDA presented data at the December 12, 2002 BPAC that Chlorhexidine in this formulation was equivalent to the iodine preparations currently in use for blood donation. In the MMWR of August 9, 2002, CDC stated that a 2% Chlorhexidine-based preparation was preferred for cutaneous antisepsis.

The 22nd edition of AABB's *Standards for Blood Banks and Transfusion Services* scheduled for implementation on November 1, 2003, will prohibit the use of green soap for cleaning the venipuncture site.

AABB Association Bulletin #03-07 and #03-10, issued Aug 2003, recommends the use of Chlorhexidine and alcohol for donors with iodine allergies.

Chlorhexidine is not specifically labeled for blood donor collection. It carries generic labeling for skin antisepsis, Blood establishments were asked to submit a prior approval supplement (PAS) to change from green soap to an arm preparation of alcohol and Chlorhexidine for donors allergic to iodine.

Issue:

CBER would need to approve a multitude of supplement applications to use a Chlorhexidine based arm prep for donors allergic to iodine in time to meet the deadline of November 1, 2003, when AABB's *Standards* go into effect.

Chlorhexidine is listed on the FDA' s website, "Options for arm Preparation", as, "method 4", of the four methods approved by the agency to prepare the phlebotomy site prior to blood and plasma collection. License establishments using 2% Chlorhexidine in 70 % isopropyl alcohol per instructions on the website may report the change in their annual report.

http://www.fda.gov/cber/blood/armpreprev.htm